UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,205	08/21/2000	Seishi Kato	GIN-6712CPUS	9088

7590 06/07/2002

Amy E Mandragouras Esq
Lahive & Cockfield
28 State Street
Boston, MA 02109

EXAMINER	
BUNNER, BRIDGET E	

ART UNIT	PAPER NUMBER
1647	19

DATE MAILED: 06/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.	Applicant(s)	
09/529,205	KATO ET AL.	
Examiner	**Art Unit**	
Bridget E. Bunner	1647	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 May 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s)

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 7-22.

Elizabeth C Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

10 ☐ Other _____

Continuation of 5. does NOT place the application in condition for allowance because:

Claims 7-22 are rejected under 35 USC § 101 (utility) and 35 USC § 112, first paragraph (enablement and written description). Applicant asserts that the present invention does satisfy 35 USC §101 and cites the Revised Interim Utility Guidelines from 21 December 1999 to emphasize that a single credible assertion of specific and substantial utility for any claimed invention satisfies the utility requirement. Applicant argues that the Revised Guidelines emphasize the importance of documentary evidence establishing one of ordinary skill in the art would disbelieve any utility described in the specification. Applicant contends that the Examiner did not provide such documentary evidence. Applicant also argues that the claimed nucleotide (SEQ ID NO: 11) encodes a secreted protein (SEQ ID NO: 1) that has sequences simliar to stem cell antigen 2 (Sca-2) and AA476643. Applicant asserts that the present invention is useful as a research tool for better characterizing the activities of stem cell antigen 2 and AA476643. Applicant's arguments have been considered but are not found persuasive for the following reasons. Applicant has not provided evidence to indicate that the polynucleotide and polypeptide of the instant application have a specific and substantial asserted utility or a well established utility. Since the specification of the instant application does not disclose any methods or working examples that indicate the polynucleotide and polypeptide of the instant application exhibit similar activities of other proteins, particularly Sca-2, the skilled artisan would not be able to categorize the polynucleotide and polypeptide of the instant application. The Examiner documented numerous references at pg 6-8 of the previous Office Action (Paper No. 17, 08 March 2002) to indicate that the regulation and sequestration of the polynucleotide and polypeptide of the instant application are not well characterized and one skilled in the art would not find the utility of the polynucleotide of SEQ ID NO: 11 and polypeptide of SEQ ID NO: 1 to be well-established, well-known, or obvious. Applicant's assertion that the isolated nucleic acid moleule of SEQ ID NO: 1 could be used as a research tool to better characterize the activities of peptides in the prior art is not credible, specific, or substantial. Such assays can be performed with any polynucleotide or polypeptide. The specification of the instant application discloses nothing specific and substantial about the claimed polynucleotides and proteins encoded by the polynucleotide and significant experimentation would be required of the skilled artisan to determine the activity of the polypeptide encoded by the claimed polynucleotide. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial. It is noted to Applicant that the Revised Interim Utility Examination Guidelines published 21 December 1999 are superseded by the revision published on 05 January 2001. Regarding the claim rejections under 35 USC §112, first paragraph, no substantially new arguments have been presented, and thus the rejections are maintained for reasons of record. It is noted that Applicant did not specifically address Examiner's arguments in the previous Office Action (Paper No. 17, 08 March 2002) regarding the use of "naturally occurring" language under 35 USC §112, first paragraph and written description under 35 USC § 112, first paragraph.